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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,117	08/06/2003	Daniel E. Couto	GTC-207	2070

31904 7590 04/15/2004

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EXAMINER
MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,117	COUTO ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1)

the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

The disclosure is objected to because of the following reasons:

The applicant has included figures in the specification on pages 28-29, 32, 38-42 and 44.

Appropriate correction is required.

There are also spaces on the following pages 27, 36 and 41 giving the indication that text might be missing form the disclosure.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** the applicant uses the phrases; "transition point flux", "pressure dependent-region" and "the transition point of the filtration". In view of the mentioned phrases, it is completely unclear as to what the applicant is claiming to be the invention. Neither of the phrases has been discussed, explained or defined anywhere in the specification. **Claims 2-70** are dependent claims that do not explain the independent claim that they depend from.

In **claim 1**, TMP needs to be spelled out in the first instance of use.

Claim 1 recites the limitation "the membrane" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim. The applicant cites a filtration membrane in the claim, if this is what the applicant is referring to, amending the claim to include the limitation "filtration" will overcome the rejection.

Claim 1 recites the limitation "the transition point" in line 10. There is insufficient antecedent basis for this limitation in the claim. The applicant cites the phrase "transition point flux" in the claim, if this is what the applicant is referring to, amending the claim to include the word "flux" will overcome the rejection.

In **claim 1** the applicant uses the phrase "TMP curve", this phrase has not been explained or defined in the specification and it is completely unclear how it relates to the invention.

In dependent **claim 7** the applicant mentions that all filtration stages are untrafiltrations, however in the independent claim 1 the applicant states that step (b) of the method is a microfiltration process. The applicant needs to amend the claims accordingly in order to overcome the rejection- because a filtration process cannot be a microfiltration process and ultrafiltration process simultaneously.

Claims 2 and 12-17 provide for the use of various filtration membranes, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In **claims 47-52** "MF" needs to be spelled out in the first instance of use.

Claims 59-69 recite the limitation "the membranes" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-10, 14-17, 22 and 70 rejected under 35 U.S.C. 102(b) as being anticipated by van Reis United States Patent 5,256,294. Van Reis teach a method for separating molecular species of interest comprising:

(a) Filtering said feed-stream by a tangential-flow filtration process through a filtration membrane having a pore size that separates said molecular species of interest from said feed-stream, while maintaining flux at a level ranging from about 5 to 100% of transition point flux in the pressure-dependent region of the flux versus TMP curve, wherein transmembrane pressure is held substantially constant along the membrane at a level no greater than the transmembrane pressure at the transition point of the filtration, whereby said molecular species of interest is selectively separated from said feed-stream such that said molecular species of interest retains its biological activity,

(b) Filtering said feed-stream by a microfiltration process; and wherein the said molecular species of interest is a protein and further comprising fractionating said feed-stream, clarifying said feed stream, diafiltering said feed stream and concentrating said feed-stream. Van Reis teaches further that the species of interest has molecular weight of about 1 to 1000 kDa and is a biopharmaceutical protein (column 5-7; column 10, lines15-68; column 11, lines 1-12; column 12 lines 14-54; example 1-3; claims 1-4, 8, 29-30 of US Patent 5,256,294) **(present claims 1-7, 9-10, 22 and 70)**. Van Reis also teaches that the filtration membrane used in the separation method is a polymeric or cellulose filtration membrane (column 12 lines 53-64) (**present claims 14-17**). Thus van Reis teaches all the elements of **claims 1-7, 9-10, 14-17, 22 and 70** and these claims are anticipated under 35 USC 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Reis United States Patent 5,256,294 in view of Kondo United States Patent 4,874,516. Van Reis teaches a method of separation as mentioned above, however van Reis does not teach the use of ceramic filters. Knodo teaches the use of ceramic filters in methods of separation (entire document). One of ordinary skill in the art would have combined van Reis and Kondo for the advantages of a method of separation using ceramic filters. Ceramic filters exhibit excellent corrosion-resistance, durability, heat resistance and therefore

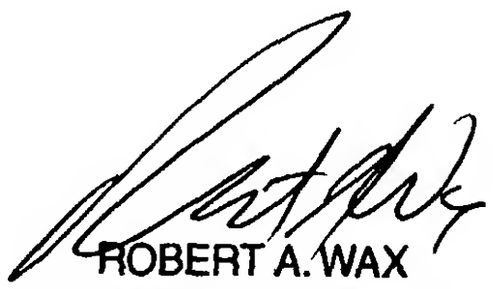
can be cleaned effectively, without being damaged, in high temperature or high pH solutions, making them a natural choice for industrial high volume use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ceramic filters in the process of van Reis with the expectation of achieving the benefits taught by Kondo. Thus the claimed invention would have been prima facie obvious at the time it was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



ROBERT A. WAX
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RBM

Robert B Mondesi
Patent Examiner
Group 1653
04-12-04